

March 18, 2013

The Honorable Terry B. Gerratana
The Honorable Susana M. Johnson
Co-Chairs, Public Health Committee
Connecticut General Assembly
Room 3000, Legislative Office Building
Hartford, CT 06106

Re: AMEND SB 1038

Dear Co-Chairs Gerratana and Johnson:

On behalf of the Connecticut Dermatology and Dermatologic Surgery Society (CDS), the American Society for Dermatologic Surgery Association (ASDSA), and the American Society for Laser Medicine and Surgery (ASLMS), we are writing to request a friendly amendment to SB 1038, which seeks to define "surgery" in statute. Our proposed friendly amendment is below in bolded red text.

No person shall, for compensation, gain or reward, received or expected, diagnose, treat, operate for or prescribe for any injury, deformity, ailment or disease, actual or imaginary, of another person, nor practice surgery, until [he] such person has obtained such a license as provided in section 20-10, and then only in the kind or branch of practice stated in such license. For purposes of this section, "surgery" means the structural alteration of the human body by an incision or destruction of tissue for the purpose of diagnostic or therapeutic treatment of conditions or disease using any instrument causing localized alteration or transposition of live human tissue which include lasers, ultrasound, ionizing radiation, scalpels, probes, and needles. but does not include procedures for the removal of superficial foreign bodies from the human body, punctures, injections, dry needling, acupuncture, the removal of dead tissue or the scraping or brushing of live tissue where such removal, scraping or brushing is accomplished without an incision causing localized alteration or transposition of live human tissue. The tissue can be cut, burned, vaporized, frozen, sutured, probed, or manipulated by closed reductions for major dislocations or fractures, or otherwise altered by mechanical, thermal, light-based, electromagnetic, or chemical means. Injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system also is considered to be surgery (this does not include the administration by nursing personnel of some injections, subcutaneous, intramuscular, and intravenous, when ordered by a physician). All of these surgical procedures are invasive, including those that are performed with lasers, and the risks of any surgical procedure are not eliminated by using a light knife or laser in place of a metal knife, or scalpel. Patient safety and quality of care are paramount and, therefore, patients should be assured that individuals who perform these types of surgery are licensed physicians (defined as doctors of medicine or osteopathy) who meet appropriate professional standards.

This language mirrors exactly policy of the American Medical Association and the American College of Surgeons. The inclusion of the use of lasers and the destruction of tissue within the definition of surgery is of particular concern to the CDS, ASDSA, and the ASLMS.

The American National Standards Institute classified IIIb and IV lasers and intense pulsed light devices are considered by the FDA to be "medical prescription devices." A "prescription device," is defined by the Code of Federal Regulations Section 801.109 as "a device which,

because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device..." As such, use of these devices should be considered the practice of medicine, and should not occur outside the supervision of a licensed and appropriately trained physician.

Any procedure, including hair removal, which utilizes energy-based devices capable of damaging living tissue performed on human beings for cutaneous conditions should be considered as the practice of surgery. Even in the case of non-ablative procedures, complications can be severe. According to "Adverse Events Associated With Nonablative Cutaneous Laser, Radiofrequency, and Light-Based Devices," (*Seminars in Cutaneous Medicine and Surgery*, Volume 26, Issue 1, March 2007, Pages 15-21), "Dyspigmentation, blistering, and even scarring may also occur and are more common in patients with darker skin types, a suntan, or when lasers in the red spectrum are used."

These procedures include but are not limited to the removal of vascular lesions, the removal of benign pigmented lesions, tattoo removal, photoepilation, and hair removal. While non-physicians may be trained on how to use a laser, they are not trained to recognize differing skin types, conditions, and diseases. According to a study published in the *Skin Therapy Letter*, "It is a truism in cutaneous laser therapy that firing a laser handpiece may be the least important portion of the treatment; it is everything but the actual treatment, including patient selection, parameter selection, and recognition and management of undesirable outcomes, that requires judgment and training."

According to unpublished data by Mathew M. Avram, MD, JD, the percentage of medical malpractice lawsuits involving the non-physician use of medical lasers has grown steadily over the past four years, from just 38 percent of lawsuits in 2008 to 78 percent of lawsuits in 2011.

For these reasons, we respectfully request SB 1038 be amended as indicated. Thank you for your consideration. For further information, please feel free to contact Debbie Osborn, Executive Director at the CDS, at eyemaster2020@yahoo.com.

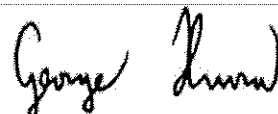
Sincerely,



Philip Kerr, MD
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Timothy C. Flynn, MD
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Association



George Hruza, MD
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